

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

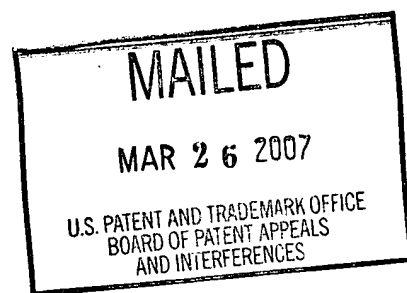
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte CHERYL D. BLUME, and ANTHONY R. DISANTO

Appeal 2007-1080
Application 10/790,658
Technology Center 1600

ON BRIEF



Before MILLS, GREEN, and LEOVITZ, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

VACATUR AND REMAND

Claims 26 and 34-62 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement (Br. 8). Claims 26 and 34-62 stand rejected under 35 U.S.C. § 103(a) as obvious over Borbe in view of Barton and Balsa (*id.*).

After considering the record before us, we find that the appealed rejection under 35 U.S.C. § 112, first paragraph, is not in condition for a decision on appeal. Accordingly, we remand this appeal to the Examiner to consider the issues discussed below and to take appropriate action not inconsistent with these views.

We also conclude that the appealed rejection under 35 U.S.C. § 103(a) does not rely on the most pertinent prior art. In particular, Milgram¹ – cited in the specification (at 5: 14) – is closer and more relevant prior art than the references now of record. For this reason, we vacate² the pending rejection under 35 U.S.C. § 103(a), and remand to the Examiner to determine whether a prior art rejection should be made over Milgram alone or in combination with other prior art.

Enablement under § 112, first paragraph

Claim 26 is drawn to a method of treating immune dysfunction that is associated with reduced levels of gamma-interferon by administering desmethylselegiline. The Examiner contends that the claimed invention is not enabled (Answer 3-6).

In rebutting the grounds of the rejection, Appellants rely on the Billiau publication which describes the role of gamma-interferon in the immune system (Br. 11). After reviewing Billiau, we find evidence in it, not addressed during prosecution, which raises questions about the adequacy of the enablement of the claimed invention provided in the application's written description. Accordingly, we remand the appeal to the Examiner to further consider this evidence. In remanding this rejection, we emphasize

¹ Milgram et al. (Milgram), U.S. Pat. 5,387,615, Feb. 7, 1995.

² Lest there be any misunderstanding, the term “vacate” in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists. *See Ex parte Zambrano*, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2000).

that the Examiner's reasons of record for finding lack of enablement were insufficient for us to decide the rejection on its merits.

Billiau teaches that gamma-interferon is known to play an important regulatory role in the immune response. To study its biological effects, gamma-interferon was administered in various *in vitro* and *in vivo* settings (e.g., Billiau at 76-81). Increased levels of gamma-interferon in these studies did not appear to always augment the immune system response. For example, Billiau reports that gamma-interferon stimulated rather than inhibited HIV viral replication (Billiau at 96). This seems to suggest that increasing gamma-interferon levels to treat AIDS as recited in claims in claims 37 and 60 would enhance the disease, rather than ameliorate it.

In addition, Billiau describes studies in which gamma-interferon enhanced tumor growth (*id.*). Treatment of cancer is recited in claims 38 and 61.

It is not clear from the record why discordant results are reported by Billiau (e.g., are they a consequence of the system not being associated with a gamma-interferon defect, or as being an artifact of the experimental system, such as a cell versus a whole animal with intact immune system). Because these issues were not fully addressed on the record before, we remand to the Examiner to reconsider the enablement issue.

Obviousness under 35 U.S.C. § 103

We find that Milgram is more pertinent prior art than any of the references now cited by the Examiner under the § 103 rejection. For this reason, we vacate the rejection and remand this proceeding to the Examiner.

Upon return of the application to the technology center, the Examiner should determine whether a § 103 rejection is appropriate in view of Milgram alone and/or combined with Borbe and Billiau. We provide the following discussion as guidance.

Milgram describes the use of L-deprenyl for treating immune system dysfunction (abstract; col. 2, ll. 60-64). L-deprenyl – also known as selegiline³ – is a selective monoamine oxidase B (MAO-B) inhibitor (col. 1, ll. 15-16). Immune system decline associated with aging is described as specific target for L-deprenyl therapy (col. 2, ll. 24-26; col. 2, l. 68 to col. 3, l. 4). This indication is also claimed by Appellant in claims 36 and 59.

Milgram also describes that administration of L-deprenyl improves the immune response to an antigen (tetanus toxoid) challenge (col. 8-9, Example 8). Instant claims 39 and 62 cover this same indication.

However, Milgram does not disclose the use of the claimed L-deprenyl metabolite, desmethyl-selegiline, to treat immune system dysfunction or to improve the immune response to an antigen.

But Borbe (abstract; pp. 135-36) teaches that the MAO-B inhibitory activity of desmethyl-selegiline is “nearly equipotent to selegiline [L-deprenyl] after multiple oral administration.” In view of Borbe’s teaching that the inhibitory activity of desmethyl-selegiline is “nearly equipotent” to L-deprenyl, the Examiner should determine whether it would have been obvious to have utilized desmethyl-selegiline to treat immune system dysfunction associated with aging or to improve the immune response, as taught by Milgram for the structurally related L-deprenyl.

³ *The Merck Index*, 12th Edition, 1448 (1996).

Milgram also shows that L-deprenyl improves T lymphocyte function (Example 2, cols. 7-8). AIDS is well-known to be associated with T lymphocyte dysfunction. In view of Milgram's teaching, the Examiner should determine whether it would have been obvious to have treated AIDS with desmethyl-selegiline as claimed in instant claims 37 and 60.

Although Milgram does not disclose that immune dysfunction in aging animals is associated with a decline in gamma-interferon as required by claim 26 and others, the disorders are the same. In view of the identity of the disorders, the Examiner should consider whether it would be reasonable to presume that immune system decline associated with aging, as taught by Milgram, would be accompanied by a reduction in gamma-interferon levels. The Examiner should make the same determination for the subject matter of claims 37, 39, 60, and 62.

Milgram also does not teach that L-deprenyl "leads to an increase in gamma-interferon production" as recited in claim 26 and others. However, "[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991). *See also In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) ("It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.") In this case, the discovery that desmethyl-selegiline increases gamma-interferon product would be considered a latent property of an otherwise obvious process.

Alternatively, Billiau teaches that gamma-interferon is produced by T lymphocytes (pp. 63-66). Consequently, the Examiner should determine

whether it would have been expected that an improvement in T lymphocyte function, as taught by Milgram (Example 2, cols. 7-8) would also be associated with increased gamma-interferon levels.

TIME PERIOD

This remand to the examiner pursuant to 37 C.F.R. § 41.50(a)(1) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)) is made for further consideration of a rejection. This application, by virtue of its “special” status, requires an immediate action. Manual of Patent Examining Procedure § 708.01(D) (8th ed., rev. Aug. 2006). It is important that the Board be informed promptly of any action affecting the appeal in this case.

VACATE AND REMAND

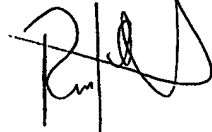

Demetra J. Mills

Administrative Patent Judge



Lora M. Green

Administrative Patent Judge



Richard M. Lebovitz

Administrative Patent Judge

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BOARD OF PATENT

APPEALS AND

INTERFERENCES

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